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<p>(21) International Application Number: PCT/SE93/00788</p> <p>(22) International Filing Date: 1 October 1993 (01.10.93)</p> <p>(30) Priority data: 9202911-5 5 October 1992 (05.10.92) SE</p> <p>(71) Applicant (for all designated States except US): AKTIEBO- LAGET ASTRA [SE/SE]; S-151 85 Södertälje (SE).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only) : HANSSON, Stig, Gus- tav, Vilhelm [SE/SE]; Gåsmossen 32, S-436 00 Askim (SE). WENNBERG, Stig, Gösta [SE/SE]; PI 6266, S-424 57 Angered (SE).</p> <p>(74) Agents: KALLING, Sven et al.; AB Astra, Patent Depart- ment, S-151 85 Södertälje (SE).</p>		<p>(81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i></p>
<p>(54) Title: FIXTURE PROVIDED WITH MICRO-THREADS</p> <div style="text-align: center; margin: 20px 0;"> </div> <p>(57) Abstract</p> <p>The present invention relates to an implant having a body (1) with at least one generally cylindrical part to be implanted into bone tissue. The cylindrical part is at least partly provided with threads (2) having a height between 0.02 mm and 0.20 mm.</p>		

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FIXTURE PROVIDED WITH MICRO-THREADS**Technical field of the invention**

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The present invention relates to an element comprising at least one cylindrical part to be implanted into bone tissue.

10 **Background to the invention**

There are two kinds of main systems for endo-osseous dental implants which are commonly used today.

15 One system utilizes fixtures provided with threads which are threaded into a hole drilled into the jaw-bone. This system can be exemplified by the so-called Brånemark system TM. This system comprises both threaded fixtures which are to be screwed into holes which have
20 been provided with threads in advance and self-tapping fixtures which are screwed into a non-pretapped hole drilled in the jaw-bone.

The other system commonly used can be exemplified by
25 the so called IMZ-implant, which utilizes a cylinder provided with a rough surface serving as a fixture and which gently is tapped into a bore-hole in the jaw-bone. The roughness of the surface has no specific orientation.

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The threaded fixtures have some important advantages, a major one being a result of the fact that the main loads in the clinical situation are axial loads. Threaded implants are very well suited to support axial
35 loads and this may be particularly important in the initial stages of the osseointegration process in which it is important that the implant is fully stable and as

immovable as possible in the bore-hole. The term
"osseo-integration" as coined by Prof Brånemark and his
coworkers in Gothenburg during the seventies and as
used here refers to the close apposition between bone
5 tissue and implants that for instance may be obtained
by using implants made of titanium.

There are however some inherent disadvantages in this
construction, one of the major ones being the time and
10 the care needed to screw a self-tapping implant into a
hole. If the hole also has to be provided with threads
in advance, the total period of time needed for the
operation of course will be much greater. Although a
conventional threaded implant conceivably could be
15 tapped into a hole having almost the same diameter as
the major diameter of the threads, the distance the
bone tissue would have to grow into the threads would
be excessive and the time needed for the osseo-
integration process would be long.

20 The rough-surfaced cylindrical implant is very simple
to insert and the time needed for this is short. It may
however happen that implants having this design gets
stuck in the bore-hole before the implant is fully
25 inserted, which may result in an unacceptable trauma to
the bone tissue, both if the implant is inserted
entirely by force and if the implant is extracted by
force. Both the initial and the final stability of the
implant will be less than the initial and the final
30 stability of a threaded implant.

Short description of the inventive concept

35 The object of the invention is to provide an implant
which combines the advantages of the two above systems
whilst eliminating the disadvantages thereof.

This object is achieved in that an endo-osseous implant is provided with the features set forth in the appended main claim.

- 5 Preferred embodiments are set forth in the appended dependent claims.

Short description of the appended drawings

- 10 Fig 1 shows an overall view of an implant according to the invention

Fig 2 shows a section of the implant in Fig 1 taken along the the line I - I

15

Fig 3 shows an end view according to the line II -II in Fig 2

- 20 Fig 4 shows a first preferred embodiment of the microthreads and Fig 5 a second preferred embodiment of the microthreads

Detailed description of preferred embodiments of the invention

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- A preferred embodiment of the invention comprises an implant having a generally cylindrical body 1 for insertion into a bore-hole in bone tissue. The envelope surface of the body 1 is provided with very small threads 2, herein called micro-threads since their dimensions are in the micrometer range. These threads will allow the implant to function as a screw. The forward end or the tip of the screw is provided with three cutting edges 4 in conjunction with chip-collecting cavities 3. A result of the presence of the chip-collecting cavities is that parts of the cylindrical part are not provided with threads. In view
- 30
- 35

of the way the implant is intended to function, an area, which is sufficient to allow the implant to function as a screw, must be provided with threads. In this preferred embodiment the tip of the body
5 furthermore is rounded in order to initially leave some space below the screw for any loose bone chips etc which might impede the full insertion of the screw. The bottom of the bore-hole is normally slightly conically shaped due to the shape of the drills normally used.

10 The cutting edges 4 and the chip-collecting cavities 3 will allow the screw, if necessary, to function as a self-tapping screw for cutting new threads or for adjusting threads already cut in the tissue.

15 The other end of the screw is, as is quite conventional in the art, provided with a longitudinal bore for the attachment of an abutment for bridging the soft tissue covering the bone tissue and for the attachment of a
20 prosthesis. The inner part 7 of the bore is cylindrical and provided with interior threads 6 and the outer part 5 of the bore is conically flaring in order to accommodate a conically tapering attachment part of an abutment ending in a cylindrical, threaded end portion.

25 Figs 4 and 5 illustrate two different embodiments of the invention. The thread shown in Fig 4 is 0.1 mm high and the distance to the adjacent thread (crest to crest) is 0.2 mm. The screw is triple-threaded, which
30 means that the pitch of the thread is 0.6 mm. The reason for the triple-threaded design rather than a single-threaded design is that the time needed for screwing the implant into the bore will be less with a multiple-threaded screw. The angle between the flanks
35 of a thread is 45°. The threads have a rounded design in order to avoid, or at least minimize, stress-concentrations in the bone tissue around the threads.

The thread shown in Fig 5 differs from the thread in fig 4 mainly in that the angle between the flanks is 60° instead of 45°.

5 Generally, the height of the micro-threads may be within the range of 0.02 - 0.20 mm. In a preferred embodiment the height may vary between 0.02 and 0.15 mm, in a more preferred embodiment between 0.05 and 0.15 and in a most preferred embodiment the height is 10 0.1 mm. The number of threads is optional but may for instance vary between 1 and 5. In a preferred embodiment the distance between adjacent threads, crest to crest, is twice the height of the threads.

15 The threads can be regarded as a defined, oriented roughness which is in the same size range as the prior art non-oriented surface roughness, for instance of the kind that can be obtained by plasma-spraying, which is a conventional technique for obtaining a surface 20 roughness on implants.

A non-oriented roughness having smaller dimensions, for instance obtained by blasting techniques, may be superimposed on the threads.

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A bio-mechanical study, (Hansson S.: On the role of surface roughness for load bearing bone implants: The retention potential of a micro-pitted surface as a function of pit size, pit shape and pit density.

30

Thesis, Centre for Biomech., Chalmers Univ. of Technol. and Gothenburg Univ., Preprint 1991:4, Gothenburg) has shown that, with a roughness of this size, a retention is obtained which is similar to the retention obtained with more coarse threads.

35

The implant can be used as both a cylindrical, rough-surfaced implant and as a threaded implant depending on

what is suitable from a medical point of view and depending on the preferences of the dentist or surgeon.

5 If the implant is used as a cylindrical implant, the implant can be lightly tapped into a hole which has the same or almost the same diameter as the major diameter as the implant (the diameter preferably should not be larger) in the same way as a conventional implant. This normally can be done relatively quickly. However,
10 should the implant get stuck half-way, which sometimes may happen, the surgeon may choose between unscrewing the implant, or screwing the implant fully into the hole. This can be done without exposing the surrounding bone tissue to the kind of trauma that would have been
15 the result if the implant were to be extracted forcibly or hammered into place by force.

New bone tissue will rapidly grow into the microthreads due to the low height of the threads and a retention
20 which is considerably better in the axial direction than in the rotational (tangential) direction will be obtained relatively quickly. This is of course a result of the fact that the threads are oriented circumferentially. Compared to an implant provided with
25 threads, an implant with a non-oriented surface roughness in the size range in question will not offer the same retention area (i. e. the area which is interlocking with the bone tissue) perpendicularly to the axial direction and consequently will not offer the
30 same degree of retention.

The design of the implant according to the invention will also permit a very gentle insertion of the implant in the upper jaw, which may be more sensitive than the
35 lower jaw. This is due to the fact that the micro-threaded implant does not require any extensive thread-cutting operations in the sometimes relatively fragile

bone tissue in the upper jaw and either can be inserted as a self-tapping screw with a minimum of cutting action or, more importantly, can be just pushed or gently tapped into a bore-hole in the upper jaw.

5

A further advantage of the invention is that also small, narrow implants will have a maximal stiffness or rigidity which may be important in view of a correct transfer of the main, axial loads to the surrounding bone tissue, since the the threads will form a comparatively small portion of the entire cross-section of the implant.

10

As mentioned above, the implant also can be used in the same way as a conventional screw-threaded implant, in which case the hole bored in the bone tissue should have a diameter corresponding to the minor diameter of the thread or somewhat larger. In the latter case, the force needed to cut the threads in the bone tissue will be less.

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It should be noted that the invention can be varied in many ways within the scope of the appended claims. It should for instance be emphasized that the invention is not limited to dental implants and that the invention could be applied to any generally cylindrical implant to be inserted into a generally cylindrical bore. Generally cylindrical in this context should be read as having parts coinciding with the envelope surface of a cylinder circumscribing the implant. A screw-shaped implant having a fluted body (in similarity with a tap) thus for instance is to be within the scope of the protection as conferred by the appended claims.

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CLAIMS

1. Implant having a body (1) with at least one generally cylindrical part to be implanted into bone tissue, c h a r a c t e r i z e d in that said cylindrical part is at least partly provided with threads (2) having a height between 0.02 mm and 0.20 mm.
2. Implant according to claim 1, c h a r a c t e r i z e d in that said threads have a height between 0.02 and 0.15 mm.
3. Implant according to claim 2, c h a r a c t e r i z e d in that said threads have a height between 0.05 and 0.15 mm.
4. Implant according to claim 3, c h a r a c t e r i z e d in that said threads have a height of 0.10 mm
5. Implant according to any one of the preceding claims, c h a r a c t e r i z e d in that the distance between adjacent threads, crest to crest, is twice the height of the threads.
6. Implant according to any one of the preceding claims, c h a r a c t e r i z e d in that the threads are multiple threads, preferably triple threads.
7. Implant according to any one of the preceding claims, c h a r a c t e r i z e d in that the angle between the flanks of the thread is 45°.
8. Implant according to any one of claims 1 - 6, c h a r a c t e r i z e d in that the angle between the flanks of the thread is 60°.

Fig 1

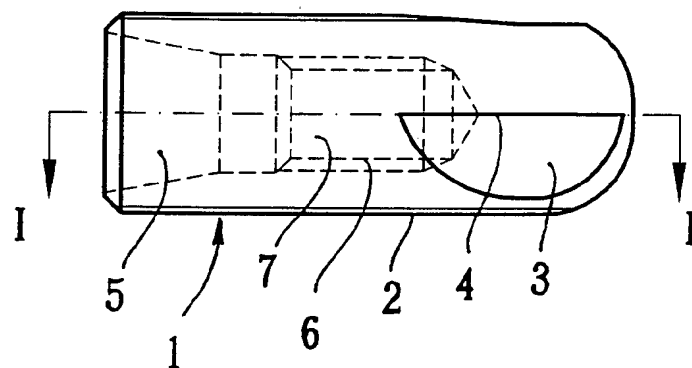


Fig 2

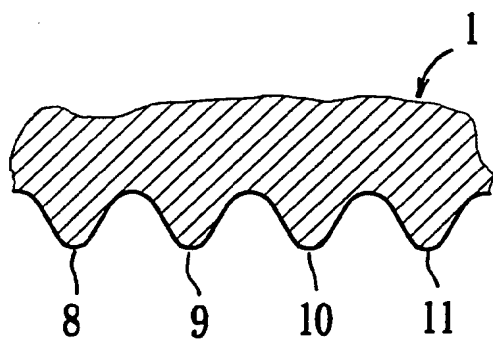
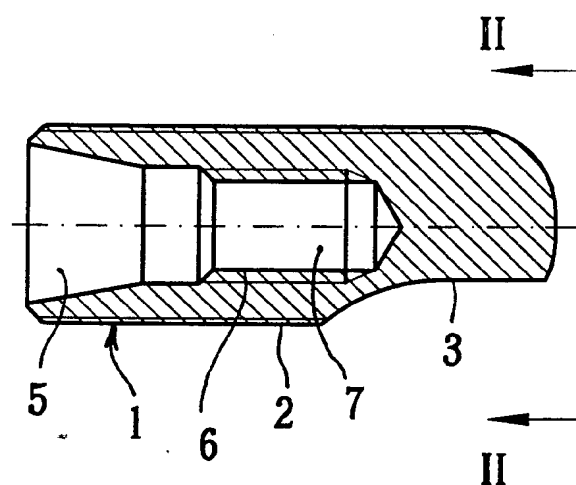


Fig 4

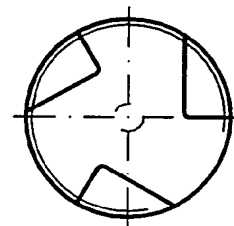


Fig 3

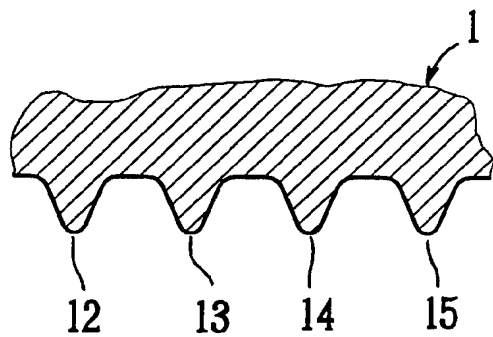


Fig 5

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 93/00788

A. CLASSIFICATION OF SUBJECT MATTER

IPC5: A61C 8/00, A61F 2/28

According to International Patent Classification (IPC) or to both national classification and IPC

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Minimum documentation searched (classification system followed by classification symbols)

IPC5: A61B, A61C, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 4790753 (FRADERA), 13 December 1988 (13.12.88), column 5, line 17 - line 30 --	1-4,7
X	US, A, 4976739 (DUTHIE, JR.), 11 December 1990 (11.12.90), column 3, line 38 - line 68; column 5, line 37 - line 39 --	1-5
A	EP, A1, 0374088 (GEBRÜDER SULZER AKTIENGESELLSCHAFT), 20 June 1990 (20.06.90), figure 7 --	1,5-6

☒ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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Swedish Patent Office

Box 5055, S-102 42 STOCKHOLM

Facsimile No. +46 8 666 02 86

Authorized officer

Leif Brander

Telephone No. +46 8 782 25 00

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4824372 (JÖRNEUS ET AL), 25 April 1989 (25.04.89), figure 1 -- -----	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

27/11/93

International application No.

PCT/SE 93/00788

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4790753	13/12/88	DE-A- 3803495 FR-A- 2610820	25/08/88 19/08/88
US-A- 4976739	11/12/90	NONE	
EP-A1- 0374088	20/06/90	CH-A- 681273	26/02/93
US-A- 4824372	25/04/89	AU-B- 601922 AU-A- 1609788 CA-A- 1295856 DE-A- 3866943 EP-A,B- 0291103	20/09/90 17/11/88 18/02/92 30/01/92 17/11/88